a practitioner's guide to

The Ultrasonic Therapy Equipment Standard

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The Ultrasonic Therapy Equipment Standard

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- Standardization of Protection Against Nonionizing Radiations
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- Nuclear Medicine

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The Ultrasonic Therapy Equipment Standard

INTRODUCTION

A performance standard for ultrasonic therapy equipment was developed by the Food and Drug Administration's Center for Devices and Radiological Health and published in the FEDERAL REGISTER on February 17, 1978 (see Appendix I). The standard requires manufacturers to meet certain criteria for equipment manufactured after February 17, 1979. These criteria require that ultrasonic therapy equipment be capable of delivering an accurate amount of ultrasonic energy to the patient. The standard also requires that sufficient information on beam characteristics be supplied to allow the practitioner to make informed judgments regarding the application of ultrasonic energy. The ultrasonic therapy equipment performance standard is aimed at assuring that patients receiving ultrasonic therapy receive the correct amount of radiation.

The purpose of this guide is to acquaint the practitioner with major provisions of the standard that will aid both in making informed judgments regarding the application of therapeutic ultrasound and in deciding on what characteristics are desired when purchasing equipment. This guide includes information that:

- States your responsibilities with regard to the use and maintenance of ultrasonic therapy equipment.
- Explains some of the important ultrasonic performance characteristics.
- Answers frequently asked questions about the ultrasonic therapy standard.

Two important points about the standard are: (1) it is an equipment performance standard and therefore it cannot specify equipment design features (the manufacturer is responsible for determining how to achieve the levels of equipment performance mandated by the standard); and (2) the standard does not regulate the use of ultrasonic therapy, i.e., it does not address the conditions for which ultrasound should be used, the personnel authorized to apply it, nor the techniques for applying it.

MAJOR PROVISIONS OF THE STANDARD

The standard specifies equipment requirements in three general areas: (1) performance especially with respect to accurately specifying the energy output; (2) labeling must state that the equipment is in compliance with the standard and include information on operating characteristics; and (3) information must be supplied with the equipment to help ensure its proper use. The major requirements are described below.

PERFORMANCE REQUIREMENTS

Output Indication

The standard imposes several requirements on manufacturers with regard to ultrasonic output. The terminology associated with the output from medical ultrasonic equipment and its relationship to terms used in the standard are provided in Appendix II. The following is a brief explanation of the ultrasonic output to facilitate understanding the requirements.

The output of a therapeutic ultrasonic unit is a beam of acoustic energy radiated from an applicator or soundhead. The beam is generated by applying a high frequency alternating current of between 0.75 and 3 MHz to a piezoelectric crystal which vibrates and emits the sound.

Prior to publishing the standard, surveys of equipment performance showed that the output meter readings on some ultrasonic units were not accurate indications of the output. Additionally, there was no convenient way to determine the degree of error between meter readings and actual output. To help solve this problem, the standard requires that each ultrasonic therapy generator have an acoustic power indicator which must be accurate to within ± 20 percent at the time the equipment is manufactured. Acoustic power is usually indicated by a meter; however, an alternative method is to label the positions of the output control with the appropriate values. Providing calibrated equipment to the practitioner at the time of sale is only the first step in ensuring that the ultrasonic therapy meter reading is an accurate indication of the output. In order to ensure accepted accuracy of the output meter reading equipment must be calibrated on a regular basis.

Some ultrasonic therapy devices are designed to radiate continuously throughout the preset treatment time. This is referred to as the *continuous mode*. Other units are designed to turn on and off at short periodic intervals, and this is referred to as the amplitude-modulated waveform operation, sometimes called pulsed (Fig. 1). The "on" time, or pulse burst width, is generally a few milliseconds. The "off" time between pulse bursts is several times longer than the pulse burst width so that the number of pulse bursts per second is generally a few hundred hertz.

When the output is amplitude-modulated, it is necessary to distinguish between the *temporal-maximum power* and the *temporal-averaged power* (Fig. 2). The actual shape of the output waveform of a pulsed unit may differ among machines from different manufacturers. In most cases, however, the output waveform will be either a square wave or a portion of a sine wave. In addition, on some units both the output pulse width and the time between pulses may each be varied.

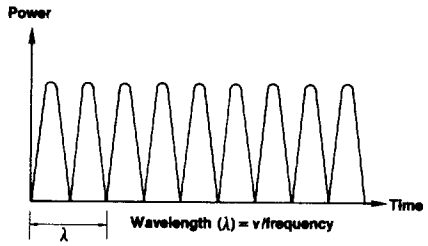

Figure 1. Types of output.

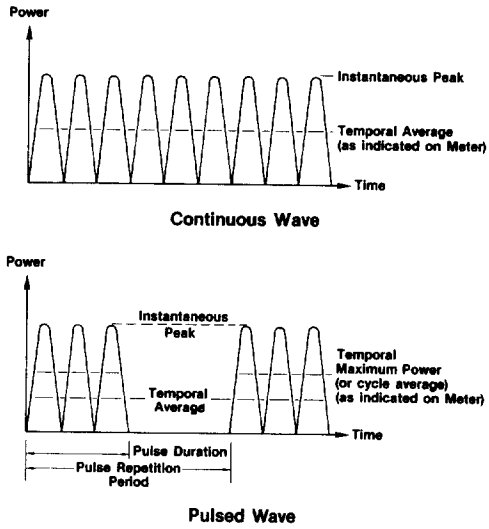

Figure 2. Comparison of continuous wave and pulsed wave. (Modified from Stewart, Repacholi, and Benwell)

The standard requires that if the generator operates in a *continuous mode*, the *temporal-averaged* power must be indicated. If the generator operates in an *amplitude-modulated mode*, the *temporal-maximum* power (i.e., the average power during the pulse) must be indicated (Fig. 2). Generators that operate in a pulsed mode may also provide an indication of the temporal-averaged power and intensity, but this is not required. Such an indication would allow for a comparison of the temporal-averaged power and intensity between pulse mode devices and continuous mode devices.

Pulse Duration and Repetition Rate Indications

Generators that operate in the pulsed mode and have controls to vary the pulse width and/or pulse repetition rate must provide the user with an indication of the magnitude of these quantities. This indication could be provided by a meter or by markings on the control itself.

Frequency Indication

Generators for which the ultrasonic frequency is variable must provide the user with an indication of the frequency being used at the treatment.

Energized Soundhead Indication

All generators must provide the user with a visual indication when electrical energy is being applied to the applicator (soundhead). If an output meter is used as the output indicator, the meter itself satisifies this requirement. If no output meter is used, this requirement can be satisfied by an indicator light.

Timer

Each ultrasonic therapy unit must have a means for automatically terminating the treatment at the end of a preset time. The preset time must be accurate as specified by the standard.

LABELING REQUIREMENTS

All labeling must meet all of the requirements of the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act and The Radiation Control for Health and Safety Act.

Certification and Identification

All ultrasonic therapy generators and applicators must bear a label indicating the manufacturer's name and address, the month and year of manufacture, and a statement certifying that the product complies with the standard. This labeling may be an actual label or it may consist of lettering on the front, sides, or rear of the unit. In addition, the labeling must state that ultrasonic therapy units shall be used only by licensed practitioners. When a generator and applicator are sold as a complete unit, the certification and identification labeling on the generator will apply to the applicator as well. When an applicator is sold separately it must either bear its own label or the label may be included in the documents accompanying the applicator.

Generator Label

In addition to the certification and identification label, each generator must bear a label identifying the model and serial number and giving certain technical information about the generator, such as the operating frequency and the type of output (continuous or pulsed). If the generator is pulsed, the label must specify the pulse width and repetition rate (unless variable), provide an actual illustration of the waveform, and give the ratio of the temporal-maximum effective intensity to the temporal-averaged effective intensity.

Applicator Label

Each ultrasonic therapy applicator, whether sold separately or as part of a generator/applicator unit, must bear a label identifying the applicator by brand name, model number, and serial number and designating the generator(s) for which

it is intended. The label must also give the operating frequency,* effective radiating area, beam nonuniformity ratio (see page 11, Beam Nonuniformity Ratio for definition), and type of applicator. Since ultrasonic therapy applicators have little available label space, abbreviations may appear on this label. When abbreviations are used, the manufacturer is required to explain them in the user information.

INFORMATION REQUIREMENTS

Service Information

The manufacturer is required to supply to servicing dealers and distributors adequate instructions for operating, servicing, and calibrating the ultrasonic therapy devices as well as a schedule of maintenance.

User Information

The manufacturer is also required to supply the user with adequate instructions for the safe use of the device, including a description of all controls and a schedule of maintenance necessary to keep the product in compliance with the standard. The user information must also include a description of the percentage uncertainties in the ultrasonic frequency, the effective radiating area, and the pulse characteristics if the generator is pulsed. In addition, the user information must include a description of the radiated sound field. The prescription legend must also be provided here.

PRACTITIONER RESPONSIBILITIES

Prior to developing the standard, surveys were conducted on the use and performance of ultrasonic therapy equipment. Surveys performed in Pinellas County, Florida and in Washington, D.C. revealed that the majority of units tested were not calibrated to within ± 20 percent. Although the standard

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*See Performance Characteristics, p. 9.

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is designed to require ultrasonic therapy equipment manufacturers to produce systems and components that perform in a prescribed way, practitioners must share the responsibility for keeping the equipment in proper operating condition. Routine quality control and recalibration of the output of ultrasonic therapy equipment is necessary to ensure that the unit provides an accurate amount of radiation throughout its recommended lifetime.

EQUIPMENT MAINTENANCE AND CALIBRATION

The standard requires ultrasonic equipment manufacturers to furnish users with a maintenance schedule that specifies how often the equipment should be recalibrated, and the procedures and precautions for the safe use of the equipment. Adherence to the schedule by users will help to assure that the unit remains in calibration. A calibrated unit provides the best assurance that the ultrasonic treatment will correspond to the output selected.

CAUTIONS TO ENSURE CALIBRATION

It is important for practitioners to recognize that when a mismatch occurs between an energized transducer and the air, most of the energy is reflected back into the transducer. When this occurs, the energy is converted to heat which can severely damage the transducer. If an energized transducer is not in contact with a medium which conducts ultrasonic energy, permanent damage to the transducer can result, causing the equipment to become uncalibrated or nonfunctional. A few newer model ultrasonic therapy units are equipped with sensors which automatically cut back on power and prevent damage to uncoupled energized transducers. However, most models currently in use are not so equipped and practitioners are cautioned against energizing them unless the transducer is adequately coupled to the patient, either via a water medium or a coupling gel.

PERFORMANCE CHARACTERISTICS

Ultrasound is a form of energy resulting from mechanical vibrations. The ultrasonic transducer produces a beam of ultrasonic waves by the vibrations of a crystal which are transferred through the metal end of the soundhead (Fig. 3). In the therapeutic setting, the propagation of ultrasonic energy through biological tissues is dependent upon the speed of sound in the tissue, the frequency, and the density of the tissue. The therapeutic effects of ultrasound are dependent upon several characteristics related to the ultrasonic beam such as frequency, power, intensity, and mode of output. This review of these important equipment characteristics will aid practitioners in understanding the terms used in the standard and in judging the adequacy of ultrasonic therapy equipment for achieving the desired clinical goal. This discussion should also facilitate the safe use of the equipment.

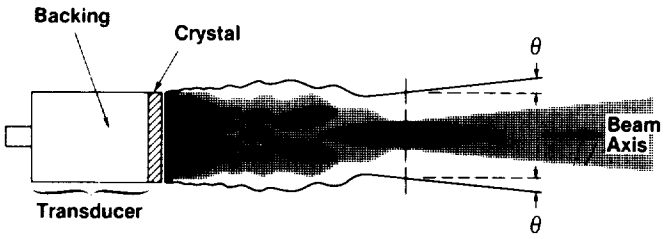

Figure 3. Schematic representation of ultrasonic beam and axial intensity profile.
(Modified from Stewart and Stratmeyer)

FREQUENCY

The number of vibrations that occur in 1 second is called the frequency. The frequency of the ultrasonic unit is not dictated by the standard. In the United States, most ultrasonic units have a frequency of 1 million cycles per second or 1 megahertz (MHz). In most cases, the frequency of each unit is fixed and cannot be varied by the practitioner. The higher the frequency the greater the absorption of energy in tissue per

unit of distance traveled. A frequency of 1 MHz is adequate for therapeutic applications since it allows for absorption of energy by the tissue at an appropriate depth.

POWER

The amount of acoustic energy per unit time is called the power. Power, expressed in watts (W), can be varied on most units from zero to 20 W. By periodically measuring the power with a wattmeter (Fig. 4) you can verify the constancy of your equipment (see Appendix III). This will allow you to deliver a known amount of energy to the patient. The ultrasonic wattmeter is relatively easy to use and is commercially available at a modest cost. All clinics should either have a wattmeter or have a service agreement with a company to periodically check the equipment.

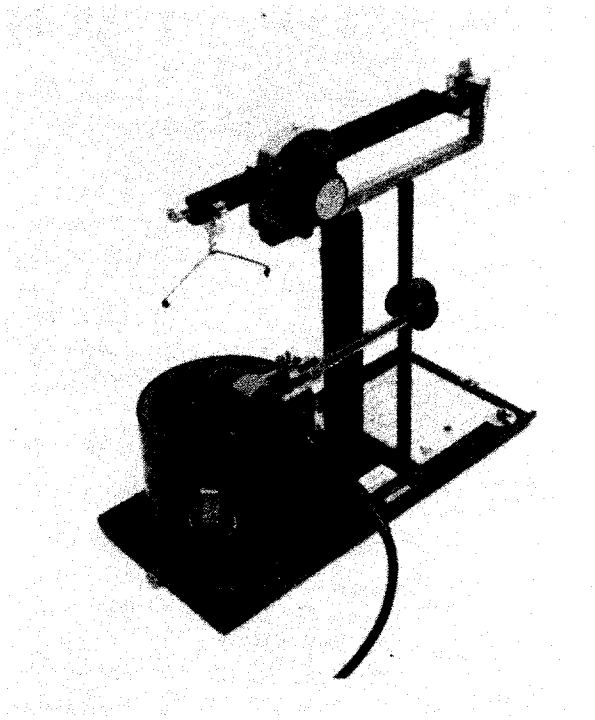

Figure 4. Wattmeter.

INTENSITY

Intensity is the characteristic most often used by practitioners in selecting the desired dosage of an ultrasonic treatment. Intensity reflects the strength of the acoustic vibrations at a given location in the tissues being treated. It is the amount of power per unit area and is expressed as watts per square centimeters (W/cm^2).

Prior to the enactment of the standard some laboratory measurements showed that large discrepancies existed between the advertised radiating area, based on transducer crystal size, and the actual radiating area. If the area were smaller than the advertised size, a higher intensity level could result than was specified. The standard requires that the effective radiating area of the applicator (soundhead) be specified on the label. This is an indication of the size of the ultrasonic beam emerging from the transducer face. The radiating area determines the average ultrasonic intensity for a given power setting. The spatial average-intensity can be obtained by dividing the ultrasonic power by the effective radiating area. For example, when a 10 cm^2 applicator radiates 20 W of ultrasonic power, the spatial average ultrasonic intensity is 2.0 W/cm^2. Many applicators have a radiating area of approximately 10 cm^2. Knowing the intensity and other exposure parameters is important in clinical research and comparative treatment studies.

BEAM NONUNIFORMITY RATIO

The ultrasonic beam distribution produced by a therapeutic transducer is nonuniform in nature. The intensity within the ultrasonic beam varies; that is, some points are higher or lower than others (Fig. 5). Thus, when an ultrasonic therapy unit is set to produce a particular intensity, say 2 W/cm^2, there will be places in the beam where the intensity is actually higher than the indicated value. A numerical measure of this nonuniformity is provided by the beam nonuniformity ratio, abbreviated BNR. The standard requires that the BNR be indicated on the applicator label. The BNR is simply the ratio

of the highest intensity in the field to the average intensity indicated on the meter. For example, if the BNR is 4.0 and the unit is set for an indicated intensity of 2.0 W/cm^2, then at some point in the beam the intensity is actually 8.0 W/cm^2. Specifying the exact location of this higher intensity is not required by the standard; however, such measurements are made by the manufacturer in order to determine the BNR. By looking at the intensity distribution provided in the user's instruction manual, some qualitative information about where the highest intensity is located can be obtained. The BNR is a useful indicator of the degree of nonuniformity. Thus, nonuniformity of the ultrasonic beam makes it essential that in the therapeutic application of ultrasound the applicator (soundhead) be moved continuously over the area being treated. This causes the energy distribution to be more uniform and areas of high temperature in the tissues are avoided.

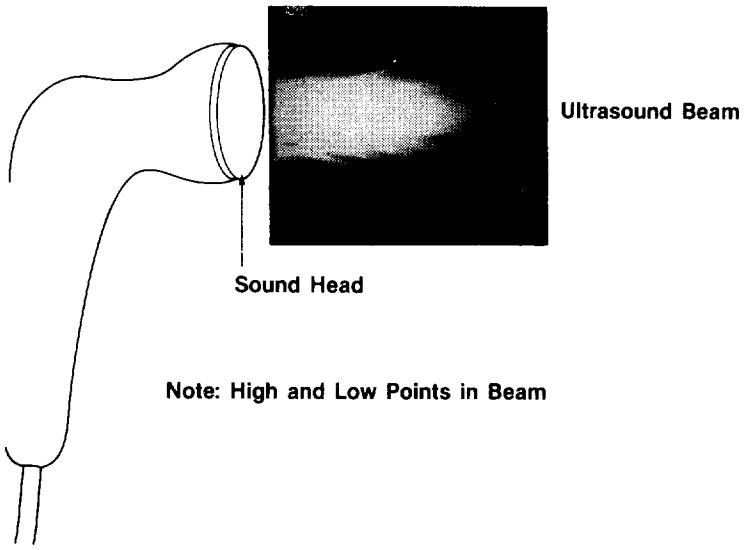

Figure 5. Schlieren photograph of an ultrasonic beam.

RECALIBRATION

The ultrasonic applicator is the major interchangeable component of ultrasonic therapy equipment. This component can be removed and replaced with another certified one. However, after replacement, the equipment must be recalibrated to maintain it in compliance. The equipment must also be recalibrated after it has been serviced or repaired.

FREQUENTLY ASKED QUESTIONS

1. Q. Is it correct to assume that the standard applies to all previously manufactured ultrasonic units currently in use?

   A. No. The standard applies only to ultrasonic units manufactured after February 17, 1979.

2. Q. Has the Federal Government adopted a standard on the *use* of ultrasonic therapy equipment?

   A. No. The existing standard applies only to the technical performance of the equipment and not to the way it is used for treatment.

3. Q. What is the practitioner's responsibility for keeping certified equipment in compliance with the standard?

   A. It is the practitioner's responsibility to have ultrasonic equipment maintained according to the schedule furnished by the manufacturer to ensure compliance with the standard for the life of the equipment. Failure to follow the manufacturer's maintenance instructions could also relieve the manufacturer of responsibility for continued compliance.

4. Q. Must leased or imported equipment meet the standard?

   A. Both leased and imported equipment must comply with the standard if the equipment was manufactured after February 17, 1979.

5. Q. Are users of ultrasonic therapy required to discard their old equipment and purchase new equipment that complies with the standard?

   A. No. There is no provision in the standard that requires the purchase of new equipment. Practitioners may continue to use equipment and components manufactured prior to February 17, 1979, even though such equipment might not comply with the standard.

6. Q. Can equipment manufactured prior to adoption of the standard be repaired without taking steps to bring the equipment into compliance?

   A. Yes. There is no certification requirement for servicing or repairing such equipment.

7. Q. What action should be taken if a newly purchased certified unit is found to be out of calibration?

   A. The first step should be to notify the manufacturer or distributor. If this is unproductive, inform the local or State radiation control agency or the nearest Food and Drug Administration Office, or both.

8. Q. How can one have ultrasonic therapy equipment calibrated?

   A. The manufacturer of the equipment is usually best qualified to calibrate it. Other facilities that may have this capability are hospital service departments, biomedical equipment and sales repair companies and authorized dealers. Keep in mind that equipment calibration should not be attempted by persons lacking the proper equipment and expertise.

9. Q. Does the output meter indicate the same intensity when the mode of delivery is switched from continuous wave to pulse wave?

   A. No. Although the numerical reading of the output meter on a given unit is the same when changing from continuous mode to pulse mode of delivery, the power output is not the same. The temporal maximum power is indicated for pulse mode operation and the temporal averaged power is indicated for continuous wave operation.

10. Q. Should an injury resulting from the use of ultrasonic equipment be reported?

    A. Yes. Practitioners and patients are encouraged to report such injuries to FDA. An incident or device related problem can be reported directly to FDA/USP's Problem Reporting Program by calling: 800-638-6725 or in Maryland call collect 301-881-0256.

APPENDIX I

Ultrasonic Therapy Products
Radiation Safety Performance Standard

(a) Applicability. The provisions of this section are applicable as specified herein to any ultrasonic therapy product for use in physical therapy manufactured on or after February 17, 1979.

(b) Definitions. The following definitions apply to words and phrases used in this section:

(1) "Amplitude modulated waveform" means a waveform in which the ratio of the temporal-maximum pressure amplitude spatially averaged over the effective radiating surface to the root-mean-square pressure amplitude spatially averaged over the effective radiating surface is greater than 1.05.

(2) "Applicator" means that portion of a fully assembled ultrasonic therapy product that is designed to emit ultrasonic radiation and which includes one or more ultrasonic transducers and any associated housing.

(3) "Beam cross-section" means the surface in any plane consisting of the points at which the intensity is greater than 5 percent of the spatial-maximum intensity in that plane.

(4) "Beam nonuniformity ratio" means the ratio of the temporal-average spatial-maximum intensity to the temporal-average effective intensity.

(5) "Centroid of a surface" means the point whose coordinates are the mean values of the coordinates of the points of the surface.

(6) "Collimating applicator" means an applicator that does not meet the definition of a focusing applicator as specified in paragraph (b)(15) of this section and for which the ratio of the area of at least one beam cross-section, whose centroid is 12

centimeters from the centroid of the effective radiating surface, to the area of the effective radiating surface is less than two.

(7) "Continuous-wave waveform" means a waveform in which the ratio of the temporal-maximum pressure amplitude spatially averaged over the effective radiating surface to the root-mean-square pressure amplitude spatially averaged over the effective radiating surface is less than or equal to 1.05.

(8) "Diverging applicator" means an applicator that does not meet the definition of a collimating applicator or a focusing applicator as specified in paragraphs (b)(6) and (15) of this section.

(9) "Effective intensity" means the ratio of the ultrasonic power to the focal area for a focusing applicator. For all other applicators, the effective intensity is the ratio of the ultrasonic power to the effective radiating area. Effective intensity is expressed in watts per square centimeter (W/cm^2).

(10) "Effective radiating area" means the area consisting of all points of the effective radiating surface at which the intensity is 5 percent or more of the maximum intensity at the effective radiating surface, expressed in square centimeters (cm^2).

(11) "Effective radiating surface" means the surface consisting of all points 5 millimeters from the applicator face.

(12) "Focal area" means the area of the focal surface, expressed in square centimeters (cm^2).

(13) "Focal length" means the distance between the centroids of the effective radiating surface and the focal surface, for a focusing applicator, expressed in centimeters (cm).

(14) "Focal surface" means the beam cross-section with the smallest area of a focusing applicator.

(15) "Focusing applicator" means an applicator in which the ratio of the area of the beam cross-section with the

smallest area to the effective radiating area is less than one-half.

(16) "Generator" means that portion of a fully assembled ultrasonic therapy product that supplies electrical energy to the applicator. The generator may include, but is not limited to, a power supply, ultrasonic frequency oscillator, service controls, operation controls, and a cabinet to house these components.

(17) "Maximum beam nonuniformity ratio" means the maximum value of the beam nonuniformity ratio characteristic of a model of an ultrasonic therapy product.

(18) "Operation control" means any control used during operation of an ultrasonic therapy product that affects the ultrasonic radiation emitted by the applicator.

(19) "Pressure amplitude" means the instantaneous value of the modulating waveform, and is $p_1(t)$ in the expression for a pressure wave, $p(t) = p_1(t)p_2(t)$, where $p(t)$ is the instantaneous pressure, $p_1(t)$ is the modulating envelope, and $p_2(t)$ is the relative amplitude of the carrier wave normalized to a peak height of one. All are periodic functions of time t, at any point in space. The period of $p_1(t)$ is greater than the period of $p_2(t)$.

(20) "Pulse duration" means a time interval, expressed in seconds, beginning at the first time the pressure amplitude exceeds the minimum pressure amplitude plus 10 percent of the difference between the maximum and minimum pressure amplitudes, and ending at the last time the pressure amplitude returns to this value.

(21) "Pulse repetition rate" means the repetition frequency of the waveform modulating the ultrasonic carrier wave expressed in pulses per second (pps).

(22) "Service control" means any control provided for the purpose of adjustment that is not used during operation and can affect the ultrasonic radiation emitted by the applicator, or

can alter the calibration or accuracy of an indicator or operation control.

(23) "Ultrasonic frequency" means the frequency of the ultrasonic radiation carrier wave, expressed in Hertz (Hz), kilohertz (kHz), or megahertz (MHz).

(24) "Ultrasonic power" means the total power emitted in the form of ultrasonic radiation by the applicator averaged over each cycle of the ultrasonic radiation carrier wave, expressed in watts.

(25) "Ultrasonic therapy product" means:

(i) Any device intended to generate and emit ultrasonic radiation for therapeutic purposes at ultrasonic frequencies above 16 kilohertz (kHz); or

(ii) Any generator or applicator designed or specifically designated for use in a device as specified in paragraph (b)(25)(i) of this section.

(26) "Ultrasonic transducer" means a device used to convert electrical energy of ultrasonic frequency into ultrasonic radiation or vice versa.

(c) Performance requirements. The requirements of this paragraph are applicable to each ultrasonic therapy product as defined in paragraph (b)(25) of this section when the generator and applicator are designated or intended for use together, or to each generator when the applicator(s) intended for use with the generator does not contain controls that affect the functioning of the generator.

(1) Ultrasonic power and intensity—(i) (Continuous-wave waveform operation. A means shall be incorporated to indicate the magnitudes of the temporal-average ultrasonic power and the temporal-average effective intensity when emission is of continuous-wave waveform. The error in the indication of the temporal-average ultrasonic power shall not exceed

± 20 percent for all emissions greater than 10 percent of the maximum emission.

(ii) Amplitude-modulated waveform operation. A means shall be incorporated to indicate the magnitudes of the temporal-maximum ultrasonic power and the temporal-maximum effective intensity when the emission is of amplitude-modulated waveform. The sum of the errors in the indications of the temporal-maximum ultrasonic power and the ratio of the temporal-maximum effective intensity to the temporal-average effective intensity specified in paragraph (d)(3)(ii) of this section shall not exceed ± 20 percent for all emissions greater than 10 percent of the maximum emission.

(2) Treatment time. A means shall be incorporated to enable the duration of emission of ultrasonic radiation for treatment to be preset and such means shall terminate emission at the end of the preset time. Means shall also be incorporated to enable termination of emission at any time. Means shall be incorporated to indicate the magnitude of the duration of emission (expressed in minutes) to within 0.5 minute of the preset duration of emission for settings less than 5 minutes, to within 10 percent of the present duration of emission for settings of from 5 minutes to 10 minutes, and to within 1 minute of the preset duration of emission for settings greater than 10 minutes.

(3) Pulse duration and repetition rate. A means shall be incorporated for indicating the magnitudes of pulse duration and pulse repetition rate of the emitted ultrasonic radiation, if there are operation controls for varying these quantities.

(4) Ultrasonic frequency. A means shall be incorporated for indicating the magnitude of the ultrasonic frequency of the emitted ultrasonic radiation, if there is an operation control for varying this quantity.

(5) Visual indicator. A means shall be incorporated to provide a clear, distinct, and readily understood visual indicator when and only when electrical energy of appropriate ultrasonic frequency is being applied to the ultrasonic transducer(s).

(d) Labeling requirements. In addition to the labeling requirements in Part 801 and the requirements of §§1010.2 and 1010.3 of this chapter, each ultrasonic therapy product shall be subject to the applicable labeling requirements of this paragraph.

(1) Operation controls. Each operation control shall be clearly labeled identifying the function controlled and, where appropriate, the units of measure of that function. If a separate control and indicator are associated with the same function, then labeling the appropriate units of measure of that function is required for the indicator but not for the control.

(2) Service controls. Each service control that is accessible without displacement or removal of any part of the ultrasonic therapy product shall be clearly labeled identifying the function controlled and shall include the phrase "for service adjustment only."

(3) Generators. (i) Each generator shall bear a label that states: The brand name, model designation, and unique serial number or other unique identification so that it is individually identifiable; ultrasonic frequency (unless there is an operation control for varying this quantity); and type of waveform (continuous wave or amplitude modulated).

(ii) Generators employing amplitude-modulated waveforms shall also bear a label that provides the following information: Pulse duration and pulse repetition rate (unless there are operation controls for varying these quantities), an illustration of the amplitude-modulated waveform, and the ratio of the temporal-maximum effective intensity to the temporal-average effective intensity. (If this ratio is a function of any operation control setting, then the range of the ratio shall be specified, and the waveform illustration shall be provided for the maximum value of this ratio.)

(4) Applicators. Each applicator shall bear a label that provides the following information:

(i) The brand name, model designation, and unique serial number or other unique identification so the applicator is individually identifiable;

(ii) A designation of the generator(s) for which the applicator is intended; and

(iii) The ultrasonic frequency, effective radiating area, maximum beam nonuniformity ratio, type of applicator (focusing, collimating, diverging), and for a focusing applicator the focal length and focal area.

(5) Label specifications. Labels required by this paragraph shall be permanently affixed to or inscribed on the ultrasonic therapy product; they shall be legible and clearly visible. If the size, configuration, or design of the ultrasonic therapy product would preclude compliance with the requirements of this paragraph, the Director, Bureau of Radiological Health, may approve alternate means of providing such label(s).

(e) Tests for determination of compliance—(1) Tests for certification. Tests on which certification pursuant to §1010.2 of this chapter is based shall account for all measurement errors and uncertainties. Such tests shall also account for increases in emission and degradation in radiation safety that occur with age.

(2) Test conditions. Except as provided in §1010.3 of this chapter, tests for compliance with each of the applicable requirements of this section shall be made:

(i) For all possible combinations of adjustments of the controls listed in the operation instructions.

(ii) With the ultrasonic radiation emitted into the equivalent of an infinite medium of distilled, degassed water at 30 °C for measurements concerning the ultrasonic radiation.

(iii) With line voltage variations in the range of ± 10 percent of the rated value specified by the manufacturer.

(3) Measurement parameters. Measurements of determination of the spatial distribution of the ultrasonic radiation field shall be made with a detector having dimensions of less than one wavelength in water or an equivalent measurement technique.

(f) Informational requirements—(1) Servicing information. The manufacturer of an ultrasonic therapy product shall provide or cause to be provided to servicing dealers and distributors, and to others upon request, at a cost not to exceed the cost of preparation and distribution, adequate instructions for operation, service, and calibration, including a description of those controls and procedures that could be used to increase radiation emission levels, and a schedule of maintenance necessary to keep equipment in compliance with this section. The instructions shall include adequate safety precautions that may be necessary regarding ultrasonic radiation exposure.

(2) User information. The manufacturer of ultrasonic therapy product shall provide as an integral part of any user instruction or operation manual that is regularly supplied with the product, or, if not so supplied, shall cause to be provided with each ultrasonic therapy product, and to others upon request, at a cost not to exceed the cost of preparation and distribution:

(i) Adequate instructions concerning assembly, operation, safe use, any safety procedures and precautions that may be necessary regarding the use of ultrasonic radiation, and a schedule of maintenance necessary to keep the equipment in compliance with this section. The operation instructions shall include a discussion of all operation controls, and shall describe the effect of each control.

(ii) Adequate description of the spatial distribution of the ultrasonic radiation field and the orientation of the field with respect to the applicator. This will include a textual discussion with diagrams, plots, or photographs representative of the beam pattern. If there is more than one ultrasonic

transducer in an applicator and their positions are not fixed relative to each other, then the description must specify the spatial distribution of the ultrasonic radiation field emitted by each ultrasonic transducer and present adequate examples of the combination field of the ultrasonic transducers with regard to safe use. The description of the ultrasonic radiation field shall state that such description applies under conditions specified in paragraph (e)(2)(ii) of this section.

(iii) Adequate description, as appropriate to the product, of the uncertainties in magnitude expressed in terms of percentage error, of the ultrasonic frequency, effective radiation area, and, where applicable, the ratio of the temporal-maximum effective intensity to the temporal-average effective intensity, pulse duration, pulse repetition rate, focal area, and focal length. The errors in indications specified in paragraph (c)(1) and (c)(2) of this section shall be stated in the instruction manual.

(iv) A listing of controls, adjustments, and procedures for operation and maintenance, including the warning "Caution—use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous exposure to ultrasonic energy."

Effective date: This regulation shall become effective February 17, 1979.

(Sec. 359, 82 Stat. 1177-1179 (21 U.S.C. 263f).)

APPENDIX II

Power and Intensity Terminology

Background

Ultrasonic therapy devices are modulated carrier wave systems, and such systems typically are described in terms of carrier wave cycle-average quantities. Thus, when the ultrasonic therapy standard was developed in 1978 the ultrasonic power was defined as a time varying quantity in terms of the cycle-average value of the ultrasonic wave. The effective intensity, a term taken from existing American National Standards Institute (ANSI) and International Electrotechnical Commission (IEC) voluntary standards, then was derived from this definition of cycle-average power, spatially averaged over the effective radiating area.

In the 1970's diagnostic ultrasound also became an important medical application, resulting in a need for the development of terms and notations to define and express the output exposure levels from diagnostic ultrasound equipment. This led to the development of a diagnostic ultrasound safety standard through the cooperative efforts of the American Institute of Ultrasound in Medicine (AIUM) and the National Electrical Manufacturers Association (NEMA) in 1981. Because pulsed diagnostic equipment primarily transmits shock excited pulses, intensity was considered to be an instantaneous quantity and the concept of averaging over a cycle was not included in the AIUM/NEMA standard. In addition, ultrasonic power was defined as being a temporal average quantity.

When the World Health Organization in 1982 and the National Council on Radiation Protection and Measurements (NCRP) in 1983 developed extensive overviews of the field, including both diagnostic and therapy exposure, the concept of a cycle-average intensity was reintroduced. The NCRP introduced the concept of a half-cycle average in terms of intensity, whereas the ultrasonic therapy standard used a carrier wave

cycle-average wave in describing the total ultrasonic power. The following tables present the description and nomenclature used by the NCRP and the ultrasonic therapy standard. The first column in each table is a notation that is compatible, where possible, with the NCRP and AIUM/NEMA notation, but expands this notation by adding the symbol "CA" to indicate cycle-average. The purpose of these tables is to provide practitioners with a way of comparing the terminology defined by the NCRP, the AIUM/NEMA, and the United States Ultrasonic Therapy Equipment Standard.

Table 1. Terminology as defined in the United States Ultrasonic Therapy Equipment Standard

Unifying Notation+	Symbol	Name and/or Description
—	W	Total ultrasonic power (cycle average or CA). (**Note**: This is a time varying quantity as defined in the therapy standard as opposed to a time averaged quantity as defined on page 60 of NCRP Report 74.)
W_{TA}	W_{TA}	Total ultrasonic power (time averaged).
W_{CA}	W_{CA}	Temporal maximum value of W, total ultrasonic power (cycle average or CA).
—	A	Effective radiating area of the applicator as defined in the therapy standard.
I_{SA}	W/A	Effective intensity is the total ultrasonic power (W) averaged over the effective radiating area (A). (**Note**: This is a spatial average quantity but does not address how it changes with time.)
*I_{SATA}	W_{TA}/A	Temporal average effective intensity is the time averaged total ultrasonic power averaged over the effective radiating area.
**$I_{SACA,T}$	W_{CA}/A	Temporal maximum effective intensity is the temporal maximum cycle average ultrasonic power averaged over the effective radiating area.

\+ The column labeled unifying notation is added to help the reader compare the terms in the therapy standard with those in the NCRP document.

* This is the intensity indicated on the meters of continuous wave ultrasonic therapy equipment.

** This is the intensity indicated on the meters of pulsed ultrasonic therapy equipment.

Table 2. Recommendations of the National Council on Radiation Protection and Measurements

The parameters listed are for a fixed transducer, especially a circular one generating a well defined beam. For pulsed operation the temporal average symbolized by ISPTA, ISATA or IT is the overall value, i.e., the averaging interval is a complete repetition period (cycle).

Unifying Notation+	NCRP Symbol	Name and/or Description
W_{TA}	W	Total emitted acoustical power (time-averaged).
I_{SPTA}	I_{SPTA} = I(SPTA)	Spatial-peak temporal-average intensity. Temporal average at the spatial peak.
I_{SATA}	I_{SATA} = I(SATA)	Time-averaged intensity spatially averaged over "effective cross-section" of beam (as defined on page 60 of NCRP Report 74).
*$I_{SATA,T}$	$I_{SATA,T}$ = I(SATA,T) = I_T	Time-average intensity at radiating face of transducer spatially averaged over effective area.
I_{SPPA}	I_{SPPA} = I(SPPA)	Spatial-peak pulse-average intensity. Intensity at spatial peak, time-averaged over pulse duration.
I_{SPTP}	i_p	For a pulse, highest of the maxima of the instantaneous intensity at the spatial peak. See text.
I_{SPCA}	I_m	Spatial peak intensity averaged over largest half-cycle of a pulse; equal to $i_p/2$ for nearly-sinusoidal oscillations. For simplicity called "maximum intensity."
**I_{SACA}	—	Spatial average intensity at radiating face of transducer averaged over largest half-cycle of a pulse.
—	A_o	Effective area of the radiating surface of a transducer (as defined on page 58 of NCRP Report 74).

\+ The column labeled unifying notation is added to help the reader compare the terms in the therapy standard with those in the NCRP document.

* This is the intensity indicated on the meters of continuous wave ultrasonic therapy equipment.

** This is the intensity indicated on the meters of pulsed ultrasonic therapy equipment.

APPENDIX III

Commercially Available Therapy Range Wattmeters

At the present time there are four known commercially available therapy range wattmeters. They are:

1. #NMY-3 Russian Wattmeter

   Source: VSESOJUZNOJE
   Exportno - Importnoje
   OBJEDINENIJE Medexport
   Moscow, USSR 121200

2. Ohmic Ultrasound Power Meter

   Source: Ohmic Instruments Co.
   St. Michaels, Maryland 21663

3. UMA

   Source: UMA, Inc.
   Route 4, Box 57
   Elkton, Virginia 22837

4. Bio-Tek UWII Wattmeter

   Source: Bio-Tek Instrument, Inc.
   One Mill Street
   Burlington, Vermont 05401